**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended June 30, 2019

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: _____ to _____

**000-30379**
*(Commission File Number)*

# Chembio Diagnostics, Inc.

*(Exact name of registrant as specified in its charter)*

| **Nevada** | **88-0425691** |
|---|---|
| *(State or other jurisdiction of incorporation)* | *(IRS Employer Identification Number)* |

**555 Wireless Blvd.**
**Hauppauge, NY 11788**
*(Address of principal executive offices including zip code)*
**(631) 924-1135**
(*Registrant's telephone number, including area code)*
N/A
*(Former Name or Former Address, if Changed Since Last Report)*

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☐
Emerging growth company ☐
Accelerated filer ☒
Smaller reporting company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
Yes ☐ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.01 par value | CEMI | The NASDAQ Stock Market LLC |

As of July 30, 2019, the registrant had 17,565,534 shares outstanding of its common stock, $.01 par value.

**Quarterly Report on Form 10-Q**
**For The Quarterly Period Ended**
**June 30, 2019**

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**Chembio Diagnostics, Inc.**



Unless the context requires otherwise, the words "we," "our," "our company," "us," "Chembio," and similar terms refer to Chembio Diagnostics, Inc. and its consolidated subsidiaries.

STAT-PAK, STAT-VIEW, SURE CHECK and DPP are our registered trademarks, and our logo design is our trademark. For convenience, these trademarks appear in this Quarterly Report on Form 10-Q supplement without ® and ™ symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks.

## NOTE ABOUT FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors, including those described or incorporated by reference in "Item 1A. Risk Factors" of Part II of this report, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements.

Any forward-looking statement made by us in this report speaks only as of the date on which it is made. Except as required by law, we assume no obligation to update these statements publicly or to update the reasons actual results could differ materially from those anticipated in these statements, even if new information becomes available in the future.

You should read this report, and the documents that we reference in this report, including exhibits that are being filed as part of this report, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

**PART I**
**Item 1. FINANCIAL STATEMENTS**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**AS OF**

| | June 30, 2019 (Unaudited) | December 31, 2018 |
|---|---|---|
| **- ASSETS -** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | **$ 4,504,075** | $ 12,524,551 |
| Accounts receivable, net of allowance for doubtful accounts of $ 42,000 at June 30, 2019 and December 31, 2018 | **7,734,006** | 7,373,971 |
| Inventories, net | **9,070,676** | 7,851,222 |
| Prepaid expenses and other current assets | **570,258** | 702,010 |
| **TOTAL CURRENT ASSETS** | **21,879,015** | 28,451,754 |
| **FIXED ASSETS:** | | |
| Property, plant and equipment, net | **3,517,701** | 2,873,920 |
| Finance lease right-of-use asset | **233,722** | - |
| | **3,751,423** | 2,873,920 |
| **OTHER ASSETS:** | | |
| Operating lease right-of-use asset | **6,949,611** | - |
| Intangible assets, net | **3,684,144** | 3,884,831 |
| Goodwill | **4,822,413** | 4,983,127 |
| Deposits and other assets | **972,675** | 717,551 |
| | **16,428,843** | 9,585,509 |
| **TOTAL ASSETS** | **$ 42,059,281** | $ 40,911,183 |
| **- LIABILITIES AND STOCKHOLDERS' EQUITY -** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable and accrued liabilities | **$ 5,317,809** | $ 5,888,681 |
| Deferred revenue | **518,410** | 422,905 |
| Current portion of note payable | **207,694** | 207,694 |
| Current portion of finance lease liability | **43,931** | - |
| Current portion of operating lease liability | **389,051** | - |
| **TOTAL CURRENT LIABILITIES** | **6,476,895** | 6,519,280 |
| **OTHER LIABILITIES:** | | |
| Operating lease liability | **6,582,446** | - |
| Finance lease liability | **189,791** | - |
| Note payable | **79,662** | 171,821 |
| Deferred tax liability | **792,587** | 892,308 |
| **TOTAL LIABILITIES** | **14,121,381** | 7,583,409 |
| **COMMITMENTS AND CONTINGENCIES** | | |
| **STOCKHOLDERS' EQUITY:** | | |
| Preferred stock - 10,000,000 shares authorized; none outstanding | **-** | - |
| Common stock - $.01 par value; 100,000,000 shares authorized; 17,565,534 and 17,166,459 shares issued and outstanding at June 30, 2019 and December 31, 2018 | **175,655** | 171,664 |
| Additional paid-in capital | **91,674,175** | 90,953,788 |
| Accumulated deficit | **(63,913,087)** | (57,909,874) |
| Accumulated other comprehensive income | **1,157** | 112,196 |
| **TOTAL STOCKHOLDERS' EQUITY** | **27,937,900** | 33,327,774 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | **$ 42,059,281** | $ 40,911,183 |

***See accompanying notes to condensed consolidated financial statements***

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | For the three months ended | | For the six months ended | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **June 30, 2019** | June 30, 2018 |
| **REVENUES:** | | | | |
| Net product sales | **$ 8,488,291** | $ 6,857,861 | **$ 14,871,277** | $ 13,256,088 |
| License and royalty revenue | **248,831** | 276,526 | **465,022** | 478,457 |
| R&D and grant revenue | **854,264** | 1,585,939 | **2,556,053** | 2,702,913 |
| **TOTAL REVENUES** | **9,591,386** | 8,720,326 | **17,892,352** | 16,437,458 |
| **COSTS AND EXPENSES:** | | | | |
| Cost of product sales | **6,693,225** | 5,935,428 | **11,463,562** | 10,053,207 |
| Research and development expenses | **2,101,020** | 1,991,412 | **4,318,652** | 3,838,514 |
| Selling, general and administrative expenses | **4,096,942** | 2,547,216 | **8,110,013** | 4,953,785 |
| Acquisition costs | **-** | - | **395,612** | - |
| | **12,891,187** | 10,474,056 | **24,287,839** | 18,845,506 |
| **LOSS FROM OPERATIONS** | **(3,299,801)** | (1,753,730) | **(6,395,487)** | (2,408,048) |
| **OTHER INCOME:** | | | | |
| Interest income, net | **5,918** | 25,355 | **12,602** | 27,330 |
| **LOSS BEFORE INCOME TAXES** | **(3,293,883)** | (1,728,375) | **(6,382,885)** | (2,380,718) |
| Income tax provision (benefit) | **(107,203)** | - | **(379,672)** | - |
| **NET LOSS** | **$ (3,186,680)** | $ (1,728,375) | **$ (6,003,213)** | $ (2,380,718) |
| **Basic loss per share** | **$ (0.19)** | $ (0.12) | **$ (0.36)** | $ (0.17) |
| **Diluted loss per share** | **$ (0.19)** | $ (0.12) | **$ (0.36)** | $ (0.17) |
| **Weighted average number of shares outstanding, basic** | **16,914,171** | 14,165,343 | **16,906,936** | 13,718,776 |
| **Weighted average number of shares outstanding, diluted** | **16,914,171** | 14,165,343 | **16,906,936** | 13,718,776 |

***See accompanying notes to condensed consolidated financial statements***

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**
**(Unaudited)**

| | For the three months ended | | For the six months ended | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **June 30, 2019** | June 30, 2018 |
| Net loss | **$ (3,186,680)** | $ (1,728,375) | **$ (6,003,213)** | $ (2,380,718) |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation adjustments | **(313,225)** | (173,828) | **(111,039)** | 78,470 |
| Comprehensive loss | **$ (3,499,905)** | $ (1,902,203) | **$ (6,114,252)** | $ (2,302,248) |

***See accompanying notes to condensed consolidated financial statements***

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**
**(Unaudited)**

| | For the six months ended June 30, 2019 | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in-Capital | Accumulated Deficit | AOCI | Total |
| | Shares | Amount | Amount | Amount | Amount | Amount |
| **Balance at December 31, 2018** | **17,166,459** | **$ 171,664** | **$ 90,953,788** | **$ (57,909,874)** | **$ 112,196** | **$ 33,327,774** |
| **Common Stock:** | | | | | | |
| Restricted stock compensation | - | - | 281,248 | - | - | 281,248 |
| **Options:** | | | | | | |
| Stock option compensation | - | - | 66,259 | - | - | 66,259 |
| **Foreign currency translation adjustments** | - | - | - | - | 202,186 | 202,186 |
| **Net loss** | - | - | - | (2,816,533) | - | (2,816,533) |
| **Balance at March 31, 2019** | **17,166,459** | **$ 171,664** | **$ 91,301,295** | **$ (60,726,407)** | **$ 314,382** | **$ 31,060,934** |
| **Common Stock:** | | | | | | |
| Restricted stock issued | 375,000 | 3,750 | (3,750) | - | - | - |
| Restricted stock compensation | - | - | 307,774 | - | - | 307,774 |
| **Options:** | | | | | | |
| Exercised | 24,075 | 241 | (241) | - | - | - |
| Stock option compensation | - | - | 69,097 | - | - | 69,097 |
| **Foreign currency translation adjustments** | - | - | - | - | (313,225) | (313,225) |
| **Net loss** | - | - | - | (3,186,680) | - | (3,186,680) |
| **Balance at June 30, 2019** | **17,565,534** | **$ 175,655** | **$ 91,674,175** | **$ (63,913,087)** | **$ 1,157** | **$ 27,937,900** |

| | For the six months ended June 30, 2018 | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in-Capital | Accumulated Deficit | AOCI | Total |
| | Shares | Amount | Amount | Amount | Amount | Amount |
| **Balance at December 31, 2017** | **12,318,570** | **$ 123,185** | **$ 62,821,288** | **$ (50,044,225)** | **$ 178,948** | **$ 13,079,196** |
| **Common Stock:** | | | | | | |
| New stock from offering | 1,783,760 | 17,838 | 10,916,514 | - | - | 10,934,352 |
| **Options:** | | | | | | |
| Exercised | 60,372 | 604 | 71,309 | - | - | 71,913 |
| Stock option compensation | - | - | 97,250 | - | - | 97,250 |
| **Foreign currency translation adjustments** | - | - | - | - | 252,298 | 252,298 |
| **Net loss** | - | - | - | (652,343) | - | (652,343) |
| **Balance at March 31, 2018** | **14,162,702** | **$ 141,627** | **$ 73,906,361** | **$ (50,696,568)** | **$ 431,246** | **$ 23,782,666** |
| **Options:** | | | | | | |
| Exercised | 10,918 | 109 | (109) | - | - | - |
| Stock option compensation | - | - | 127,035 | - | - | 127,035 |
| **Foreign currency translation adjustments** | - | - | - | - | (173,828) | (173,828) |
| **Net loss** | - | - | - | (1,728,375) | - | (1,728,375) |
| **Balance at June 30, 2018** | **14,173,620** | **$ 141,736** | **$ 74,033,287** | **$ (52,424,943)** | **$ 257,418** | **$ 22,007,498** |

***See accompanying notes to condensed consolidated financial statements***

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**FOR THE SIX MONTHS ENDED**
**(Unaudited)**

| | June 30, 2019 | June 30, 2018 |
|---|---|---|
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Cash received from customers and grants | **$ 17,627,823** | $ 12,247,228 |
| Cash paid to suppliers and employees | **(24,421,683)** | (17,352,226) |
| Cash paid for operating leases | **(305,157)** | - |
| Interest received, net | **12,602** | 27,330 |
| **Net cash used in operating activities** | **(7,086,415)** | (5,077,668) |
| | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Patent application costs | **(72,295)** | - |
| Acquisition of and deposits on fixed assets | **(1,077,203)** | (250,147) |
| Working capital adjustment related to business combination | **145,760** | - |
| **Net cash used in investing activities** | **(1,003,738)** | (250,147) |
| | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from option exercises | - | 71,914 |
| Payments on note payable | **(92,158)** | - |
| Proceeds from sale of common stock, net | - | 10,934,352 |
| **Net cash (used in) provided by financing activities** | **(92,158)** | 11,006,266 |
| | | |
| Effect of exchange rate changes on cash | **161,835** | 37,029 |
| **(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS** | **(8,020,476)** | 5,715,480 |
| Cash and cash equivalents - beginning of the period | **12,524,551** | 3,790,302 |
| | | |
| **Cash and cash equivalents - end of the period** | **$ 4,504,075** | $ 9,505,782 |
| | | |
| **RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:** | | |
| | | |
| **Net loss** | **$ (6,003,213)** | $ (2,380,718) |
| Adjustments: | | |
| Depreciation and amortization | **750,322** | 446,625 |
| Share based compensation | **724,378** | 224,283 |
| Provision for (benefit from) deferred tax liability | **(379,672)** | - |
| Changes in assets and liabilities: | | |
| Accounts receivable | **(360,037)** | (4,800,979) |
| Inventories | **(1,219,454)** | (1,926,022) |
| Prepaid expenses and other current assets | **131,752** | (215,758) |
| Deposits and other assets | **(255,124)** | - |
| Accounts payable and accrued liabilities | **(570,872)** | 2,964,151 |
| Deferred revenue | **95,505** | 610,750 |
| **Net cash used in operating activities** | **$ (7,086,415)** | $ (5,077,668) |
| | | |
| **Supplemental disclosures for non-cash investing and financing activities:** | | |
| Deposits on manufacturing equipment transferred to fixed assets | **$ -** | $ 257,455 |
| Seller-financed equipment purchases | - | 327,070 |

***See accompanying notes to condensed consolidated financial statements***

**NOTE 1 — DESCRIPTION OF BUSINESS:**

Chembio Diagnostics, Inc. and its subsidiaries (collectively, the "Company" or "Chembio") develop, manufacture, and commercialize point-of-care ("POC") diagnostic tests that are used to detect or monitor diseases. The Company's product development efforts are focused on its patented DPP technology, a novel POC diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology. POC tests, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POC tests can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

Our product commercialization and product development efforts are focused in two areas: infectious disease, which includes both sexually transmitted and tropical & fever disease; and strategic collaborations with leading global healthcare companies, which leverage the DPP platform to provide us with additional revenue streams. In infectious disease, we are commercializing tests for HIV, Syphilis, Zika virus, dengue virus, chikungunya virus, , and ebola, and developing tests for hepatitis C, malaria, lassa, Marburg, leptospirosis, *Rickettsia typhi*, *Burkholderia pseudomallei*, and *Orientia tsutsugamushi*. Certain of these are also being developed as part of fever panel tests. Through strategic collaborations, we are developing tests for a specific form of cancer, concussions, bovine tuberculosis, and for eosinophilic respiratory disease, the latter in collaboration with global biopharmaceutical company AstraZeneca. As noted above, we are also developing a point-of-care test for an undisclosed biomarker for Takeda, also a global pharmaceutical company.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are critical for large scale prevention and treatment programs. The Company's product development is focused on areas where the availability of rapid, POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally, the Company believes there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally, under its STAT-PAK, SURE CHECK, STAT-VIEW and DPP registered trademarks, or under the private labels of its marketing partners.

The Company routinely enters into arrangements with governmental and non-governmental organizations for the funding of certain research and development efforts.

**NOTE 2 — ACQUISITION:**

On November 6, 2018, pursuant to a share purchase agreement, the Company acquired all of the outstanding shares of opTricon GmbH ("opTricon"), a privately-held Germany based developer and manufacturer of handheld analyzers for rapid diagnostic tests, for $5.5 million in cash, subject to routine post-closing adjustments. Since 2015, the Company and opTricon have been parties to an agreement under which the Company has collaborated in developing its DPP Micro Reader, a handheld, battery-operated analyzer that uses an innovative image sensor to provide, when combined with the Company's DPP tests, a quantitative interpretation of diagnostic results. The Company purchased opTricon because it believes it will enable it to promote DPP tests and DPP Micro Reader more actively across global markets. The results of opTricon operations have been reflected in the consolidated financial statements since November 6, 2018.

As a result of the consideration paid exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of $3,337,000 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $2,260,000 in intangible assets associated with the addition of opTricon's developed technology and customer base. During the six months ended June 30, 2019, the Company reduced Goodwill by $145,760 related to routine post-closing adjustments. The Consolidated Statements of Operations for the three and six months ended June 30, 2019 include $0 and $395,612 of transaction costs related to the opTricon acquisition.

The acquisition was accounted for using the purchase method of accounting. The following table summarizes the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of November 6, 2018:

| | Amount |
|---|---|
| Net current assets | $ 404,204 |
| Property, plant and equipment | 125,000 |
| Goodwill | 3,337,000 |
| Deferred tax liability | (635,000) |
| Other intangible assets (estimated useful life): | |
| Developed technology (7 years) | 1,900,000 |
| Customer contracts / relationships (10 years) | 360,000 |
| Total consideration | $ 5,491,204 |

The Company calculated the fair value of the fixed assets based on the net book value of opTricon as that approximates fair value. The developed technology and customer contracts/relationships were based on discounted cash flows using management estimates.

As indicated, the allocation of the purchase price shown above is preliminary, pending completion of an analysis of the deferred tax liability. Therefore, an adjustment may be required.

**NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

***a) Basis of Presentation:***

The preceding (a) condensed consolidated balance sheet as of December 31, 2018, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of June 30, 2019 and for the three and six-month period ended June 30, 2019 and 2018 have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures, which are normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations, although the Company believes that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 18, 2019.

Our future working capital needs will depend on many factors, including the rate of our business and revenue growth, the timing of our continuing automation of U.S. manufacturing, and the timing of investment in our research and development as well as sales and marketing. If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, we may need to reduce the level or slow the timing of the growth plans contemplated by our operating plan, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of the Company's condensed consolidated financial position as of June 30, 2019 and, its condensed consolidated results of operations for the three and six-month period ended June 30, 2019 and 2018 have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

***b) Revenue Recognition:***

In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and in certain circumstances, allowing estimates of variable consideration to be recognized before contingencies are resolved. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers.

The new revenue standards became effective for the Company on January 1, 2018 and were adopted using the modified retrospective method. The adoption of the new revenue standards as of January 1, 2018 did not change the Company's revenue recognition as its revenues continue to be recognized when the customer takes control of its product. As the Company did not identify any material accounting changes that impacted the amount of reported revenues with respect to its product revenue, license and royalty revenue, and research and development ("R&D") and grant revenues, no adjustment to retained earnings was required upon adoption.

The Company adopted the standards for contracts that were not completed at the date of initial application (January 1, 2018).

Under the new revenue standards, the Company recognizes revenues when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company recognizes revenues following the five-step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) the Company satisfies the performance obligations.

*Product Revenues*

Revenues from product sales are recognized and commissions are accrued when the customer obtains control of the Company's product, which occurs at a point in time, typically upon tendering to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial. Freight and distribution activities on products are performed after the customer obtains control of the goods. The Company has made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in cost of product sales.

The Company's payment terms vary by the type and location of the Company's customer and products or services offered. Payment terms differ by jurisdiction and customer but payment is generally required in a term ranging from 30 to 60 days from date of shipment or satisfaction of the performance obligation.

*Reserves for Discounts and Allowances*

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers. The Company's process for estimating reserves established for these variable consideration components does not differ materially from its historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally related to discounts. Estimates of variable consideration and the determination of whether to include estimated amounts in the transaction price are based on all information (historical, current and forecasted) that is reasonably available to the Company, taking into consideration the type of customer, the type of transaction and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

*Royalty Revenues*

The Company receives royalty revenues on sales by its licensees of products covered under patents that it owns. The Company does not have future performance obligations under these license arrangements. The Company records these revenues based on estimates of the sales that occurred during the relevant period as a component of license and royalty revenues. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties that have been paid to the Company, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. Historically, adjustments have not been material when compared to actual amounts paid by licensees.

*R&D and Grant Revenue*

All R&D and grant contracts are evaluated under the five-step model described above. For certain contracts that represent grants where the funder does not meet the definition of a customer, the Company recognizes revenue when earned in accordance with ASU No. 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and Accounting Guidance for Contributions Received and Contributions Made*. Such contracts are further described under *Disaggregation of Revenue*, below. Grants are invoiced and revenue is recognized as expenses are incurred as that is the depiction of the timing of the transfer of services. Performance obligations generally follow the major phases of product development processes: design feasibility & planning, product development & design optimization, design verification, design validation & process validation, and pivotal studies.

*Disaggregation of Revenue*

The following tables disaggregate Total Revenues.

| | For the three months ended June 30, 2019 | | | For the three months ended June 30, 2018 | | |
|---|---|---|---|---|---|---|
| | **Exchange Transactions** | **Non-Exchange Transactions** | **Total** | Exchange Transactions | Non-Exchange Transactions | Total |
| Net product sales | **$ 8,488,291** | **$ -** | **$ 8,488,291** | $ 6,857,861 | $ - | $ 6,857,861 |
| License and royalty revenue | **248,831** | **-** | **248,831** | 276,526 | - | 276,526 |
| R&D and grant revenue | **619,139** | **235,125** | **854,264** | 755,570 | 830,369 | 1,585,939 |
| | **$ 9,356,261** | **$ 235,125** | **$ 9,591,386** | $ 7,888,957 | $ 830,369 | $ 8,720,326 |

| | **Total** | Total |
|---|---|---|
| Africa | **$ 2,342,740** | $ 2,226,540 |
| Asia | **119,548** | 22,348 |
| Europe & Middle East | **1,107,558** | 1,213,548 |
| Latin America | **4,612,904** | 3,266,290 |
| United States | **1,408,636** | 1,991,600 |
| | **$ 9,591,386** | $ 8,720,326 |

| | For the six months ended June 30, 2019 | | | For the six months ended June 30, 2018 | | |
|---|---|---|---|---|---|---|
| | **Exchange Transactions** | **Non-Exchange Transactions** | **Total** | Exchange Transactions | Non-Exchange Transactions | Total |
| Net product sales | **$ 14,871,277** | **$ -** | **$ 14,871,277** | $ 13,256,088 | $ - | $ 13,256,088 |
| License and royalty revenue | **465,022** | **-** | **465,022** | 478,457 | - | 478,457 |
| R&D and grant revenue | **1,392,204** | **1,163,849** | **2,556,053** | 1,367,375 | 1,335,538 | 2,702,913 |
| | **$ 16,728,503** | **$ 1,163,849** | **$ 17,892,352** | $ 15,101,920 | $ 1,335,538 | $ 16,437,458 |

| | **Total** | Total |
|---|---|---|
| Africa | **$ 4,759,040** | $ 3,865,070 |
| Asia | **240,646** | 989,922 |
| Europe & Middle East | **3,250,779** | 2,197,424 |
| Latin America | **5,684,970** | 5,956,183 |
| United States | **3,956,917** | 3,428,859 |
| | **$ 17,892,352** | $ 16,437,458 |

Exchange transactions are recognized in accordance with ASU No. 2014.09, and non-exchange transactions are recognized in accordance with ASU No. 2018.08.

*Contract Liabilities*

Deferred revenue relates to payments received in advance of performance under the contract. Deferred revenue is recognized as revenue as (or when) the Company performs under the contract. At December 31, 2018, the Company reported $422,905 in deferred revenue of which $422,905 was earned and recognized as R&D and grant revenue during the six months ended June 30, 2019. At June 30, 2019, the Company reported $518,410 in deferred revenue that is expected to be recognized during the second half of 2019.

***c) Inventories***

Inventories consist of the following at:

| | **June 30, 2019** | December 31, 2018 |
|---|---|---|
| Raw materials | **$ 2,834,559** | $ 2,803,677 |
| Work in process | **1,556,944** | 263,043 |
| Finished goods | **4,679,173** | 4,784,502 |
| | **$ 9,070,676** | $ 7,851,222 |

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost and net realizable value. Cost is determined on the first-in, first-out method. The Company's policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a write-down for any inventory considered slow moving or obsolete. There were reserves against inventory of approximately $67,000 and $78,000 as of June 30, 2019 and December 31, 2018, respectively.

***d) Loss Per Share:***

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period excluding unvested restricted stock. Diluted loss per share for the three and six-month periods ended June 30, 2019 and 2018 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 688,122 and 683,829 weighted-average number of options outstanding as of June 30, 2019 and 2018, respectively, that were not included in the calculation of diluted per common share equivalents for the three months ended June 30, 2019 and 2018, respectively, because the effect would have been anti-dilutive. There were 686,609 and 707,880 weighted-average number of options outstanding as of June 30, 2019 and 2018, respectively, that were not included in the calculation of diluted per common share equivalent for the six months ended June 30, 2019 and 2018, respectively, because the effect would have been anti-dilutive.

***e) Stock Incentive Plan:***

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 the Company's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, which expired during 2018, the Board of Directors or its Compensation Committee had the discretion to select the persons to whom awards were to be granted. Awards could be stock options, restricted stock and/or restricted stock units ("Equity Award Units"). The Equity Award Units became vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through June 30, 2019, there were 508,889 options exercised, and at June 30, 2019, 99,132 options were outstanding and no Equity Award Units were available to be issued under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("SIP14"), with 800,000 shares of common stock available to be issued. Under the terms of the SIP14, the Board or its Compensation Committee has the discretion to select the persons to whom Equity Award Units were to be granted. Awards can be in the form of Equity Award Units. The Equity Award Units vest at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through June 30, 2019, there were 132,282 options exercised, and at June 30, 2019, 344,093 options were outstanding. Upon approval of the 2019 Plan (defined below), no additional Equity Award Units could be issued under the SIP14. During 2018, 266,839 shares of restricted stock and 20,725 restricted stock units were awarded under SIP14.

Effective June 18, 2019, the Company's stockholders voted to approve the 2019 Omnibus Incentive Plan ("2019 Plan"), with 2,400,000 shares of Common Stock available to be issued. Under the terms of the 2019 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of Equity Award Units. The awards vest at such times and under such conditions as determined by the Compensation Committee. As of June 30, 2019, 375,000 shares of restricted stock had been awarded under the 2019 Plan, no options had been issued under the 2019 Plan. 2,025,000 Equity Award Units were available to be issued.

***f) Stock-Based Compensation:***

The fair value of restricted stock and restricted stock unit awards are their fair value on the date of grant. Stock-based compensation expense for stock options is calculated using the Black-Scholes valuation model based on awards ultimately expected to vest, together with the fair value of restricted stock and restricted stock unit awards, are reduced for actual forfeitures and expensed on a straight-line basis over the requisite service period of the grant.

Stock option compensation expense in each of the periods presented represents the estimated fair value of unvested, outstanding options, amortized on a straight-line basis over the requisite vesting periods of the entire awards.

Stock-based compensation expense recognized in the condensed consolidated statements of operations was classified as follows:

| | **For the three months ended** | | **For the six months ended** | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **June 30, 2019** | June 30, 2018 |
| Cost of product sales | **$ 2,300** | $ 5,800 | **$ 5,800** | $ 14,000 |
| Research and development expenses | **56,300** | 3,600 | **116,100** | 15,500 |
| Selling, general and administrative expenses | **318,300** | 117,700 | **602,500** | 194,800 |
| | **$ 376,900** | $ 127,100 | **$ 724,400** | $ 224,300 |

The weighted-average assumptions made in calculating the fair values of options are as follows:

| | For the three months ended | | For the six months ended | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **June 30, 2019** | June 30, 2018 |
| Expected term (in years) | N/A | 5.4 | N/A | 5.4 |
| Expected volatility | N/A% | 40.12% | N/A% | 40.12% |
| Expected dividend yield | N/A% | 0% | N/A% | 0% |
| Risk-free interest rate | N/A% | 2.70% | N/A% | 2.70% |

The following table provides stock option activity for the six months ended June 30, 2019:

| Stock Options | Number of Shares | Weighted Average Exercise Price per Share | Weighted Average Remaining Contract Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| **Outstanding at December 31, 2018** | **711,968** | **$ 5.62** | **3.33 years** | **$ 687,364** |
| Granted | - | - | | - |
| Exercised | 46,875 | 3.48 | | 172,242 |
| Forfeited/expired/cancelled | 15,000 | 5.68 | | 30,286 |
| **Outstanding at June 30, 2019** | **650,093** | **$ 5.77** | **3.04 years** | **$ 719,362** |
| **Exercisable at June 30, 2019** | **429,009** | **$ 4.82** | **2.37 years** | **$ 703,769** |

The following table summarizes information about stock options outstanding at June 30, 2019:

| | Stock Options Outstanding | | | | Stock Options Exercisable | | |
|---|---|---|---|---|---|---|---|
| Range of Exercise Prices | Number of Shares | Average Remaining Contract Term (Year) | Weighted Average Exercise Price | Aggregate Intrinsic Value | Number of Shares | Weighted Average Exercise Price | Aggregate Intrinsic Value |
| 1 to 2.79999 | - | - | $ - | $ - | - | $ - | $ - |
| 2.8 to 4.59999 | 257,468 | 1.67 | 3.44 | 681,419 | 257,468 | 3.44 | 681,419 |
| 4.6 to 6.39999 | 137,875 | 2.95 | 5.87 | 37,943 | 77,750 | 5.87 | 22,350 |
| 6.4 to 8.19999 | 207,875 | 4.56 | 7.31 | - | 84,416 | 7.32 | - |
| 8.2 to 12 | 46,875 | 4.11 | 11.45 | - | 9,375 | 11.45 | - |
| Total | 650,093 | 3.04 | $ 5.77 | $ 719,362 | 429,009 | $ 4.82 | $ 703,769 |

As of June 30, 2019, there was $562,488 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted average period of approximately 2.0 years. The total fair value of shares vested during the six-month periods ended June 30, 2019 and 2018 was $235,578 and $319,549, respectively.

The following table summarizes information about restricted stock and restricted stock units outstanding as of June 30, 2019:

| | Number of Shares & Units | Weighted Average Grant Date Fair Value |
|---|---|---|
| **Outstanding at December 31, 2018** | 287,564 | $ 9.65 |
| Granted | 375,000 | 5.80 |
| Earned/released | - | - |
| Forfeited/expired/cancelled | - | - |
| **Outstanding at June 30, 2019** | **662,564** | **$ 7.47** |

As of June 30, 2019, there was $4,079,720 of net unrecognized compensation cost related to restricted stock and restricted stock units that had not vested, which is expected to be recognized over a weighted average period of approximately 2.42 years.

***g) Geographic Information and Economic Dependency***

The Company produces only one group of similar products known collectively as "rapid medical tests", and it operates in a single business segment. Net product sales by geographic area were as follows:

| | For the three months ended | | For the six months ended | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **June 30, 2019** | June 30, 2018 |
| Africa | **$ 2,342,740** | $ 2,226,540 | **$ 4,759,040** | $ 3,865,070 |
| Asia | **119,548** | 22,348 | **240,646** | 989,922 |
| Europe & Middle East | **741,641** | 635,579 | **1,919,666** | 1,027,649 |
| Latin America | **4,612,904** | 3,266,290 | **5,684,970** | 5,956,183 |
| United States | **671,458** | 707,104 | **2,266,955** | 1,417,264 |
| | **$ 8,488,291** | $ 6,857,861 | **$ 14,871,277** | $ 13,256,088 |

Long-lived assets by geographic area were as follows at:

| | **June 30, 2019** | December 31, 2018 |
|---|---|---|
| Asia | **459,978** | 466,185 |
| Europe & Middle East | **169,147** | 123,752 |
| United States | **2,888,576** | 2,283,983 |
| | **$ 3,517,701** | $ 2,873,920 |

***h) Fair Value of Financial Instruments:***

The carrying values for cash and cash equivalents, accounts receivable, and accounts payable approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents were $3.3 million and $4.7 million as of June 30, 2019 and December 31, 2018, respectively, of money market funds that are Level 1 fair value measurements under the hierarchy. The fair value of the Company's note payable approximates the recorded value as the rate is based upon the current rates offered to the Company for similar financial instruments.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and,

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

***i) Accounts Payable and Accrued Liabilities:***

Accounts payable and accrued liabilities consisted of:

| | **June 30, 2019** | December 31, 2018 |
|---|---|---|
| Accounts payable – suppliers | **$ 3,292,605** | $ 3,622,765 |
| Accrued commissions and royalties | **715,177** | 867,344 |
| Accrued payroll | **352,689** | 48,867 |
| Accrued vacation | **606,110** | 264,789 |
| Accrued bonuses | **314,565** | 494,318 |
| Accrued expenses – other | **36,663** | 590,598 |
| TOTAL | **$ 5,317,809** | $ 5,888,681 |

***j) Goodwill Long-Lived Assets and Intangible Assets:***

Goodwill represents the excess of the purchase price the Company paid over the fair value of the net tangible and identifiable intangible assets acquired in the Company's acquisition of opTricon in November 2018 and Chembio Diagnostics Malaysia Sdn Bhd in January 2017. Goodwill is not amortized but rather is tested annually as of the first day of the fiscal fourth quarter for impairment or more frequently if the Company believes that indicators of impairment exist. The Company makes a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If the Company concludes that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then the Company recognizes an impairment charge for the amount by which the carrying value exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

Following is a table that reflects changes in goodwill:

| | |
|---|---|
| Beginning balance December 31, 2018 | $ 4,983,127 |
| opTricon measurement period adjustment | (145,760) |
| Change in foreign currency exchange rate | (14,954) |
| Balance at June 30, 2019 | $ 4,822,413 |

Intangible assets consisted of the following at:

| | | June 30, 2019 | | | December 31, 2018 | | |
|---|---|---|---|---|---|---|---|
| | **Weighted Average Useful Life** | **Cost** | **Accumulated Amortization** | **Net Book Value** | Cost | Accumulated Amortization | Net Book Value |
| Intellectual property | 10 | $ 1,161,984 | $ 232,157 | $ 929,827 | $ 1,089,688 | $ 173,633 | $ 916,055 |
| Developed technology | 7 | 1,890,261 | 154,128 | 1,736,133 | 1,910,315 | - | 1,910,315 |
| Customer contracts/relationships | 8 | 1,174,664 | 240,159 | 934,505 | 1,121,600 | 151,929 | 969,671 |
| Trade names | 9 | 108,521 | 24,842 | 83,679 | 108,521 | 19,731 | 88,790 |
| | | $ 4,335,430 | $ 651,286 | $ 3,684,144 | $ 4,230,124 | $ 345,293 | $ 3,884,831 |

Intellectual property, developed technology, customer contracts/relationships, and trade names are amortized over 10, 7, 10, and 11 years, respectively. Amortization expense for the six months ended June 30, 2019 and 2018 was approximately $306,700 and $45,000, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to be $497,761 per year from 2019 through 2023, and total $1,406,081 for all of the years thereafter.

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value.

No impairment of goodwill, long-lived tangible, and intangible assets was recorded for the six months ended June 30, 2019 and 2018.

***k) Taxes:***

At the end of each interim reporting period, the Company estimates its effective tax rate expected to be applied for the full year. This estimate is used to determine the income tax provision or benefit on a year-to-date basis, and may change in subsequent interim periods. Accordingly, the Company's effective tax benefit for the three and six-month periods ended June 30, 2019 were 3.3% and 6.0%, compared to the effective tax rate of 0.0% and 0.0%, respectively, for the three and six-month periods ended June 30, 2018. The Company's effective tax rates for both periods were affected primarily by a full valuation allowance on domestic net deferred tax assets and the benefit from foreign net operating losses.

***l) Research and Development:***

R&D costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

***m) Allowance for Doubtful Accounts:***

The Company records allowances for doubtful accounts for the estimated probable losses on uncollectible accounts receivable. The allowance is based upon the credit worthiness of the Company's customers, the Company's historical experience, the age of the receivable and current market and economic conditions. Receivables are written off against these allowances in the period they are determined to be uncollectible.

***n) Acquisition Costs:***

Acquisition costs include period expenses, primarily professional services, related to acquisition activities.

***o) Foreign Currency Translation:***

The functional currency of a foreign subsidiary is the local currency. Assets and liabilities of foreign subsidiaries that use a currency other than U.S. dollars as their functional currency are translated to U.S. dollars at end of period currency exchange rates. The consolidated statements of operations of foreign subsidiaries are translated to U.S. dollars at average period currency exchange rates. The effect of translation for foreign subsidiaries is generally reported in Other Comprehensive Income. Foreign transaction gains are immaterial.

***p) Recent Accounting Pronouncements Affecting the Company:***

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU No. 2016-02 requires the entity to recognize the assets and liabilities for the rights and obligations created by leased assets. Leases are to be classified as either finance or operating, with classification affecting expense recognition in the income statement. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which provide supplemental adoption guidance and clarification to ASU No. 2016-02, which must be adopted concurrently with the adoption of ASU No. 2016-02 and which are cumulatively referred to as "Topic 842". Topic 842 was effective for the Company in the first quarter of 2019, and is to be applied using either a modified retrospective approach or an optional transition method, which allows an entity to apply the new standard at the adoption date with a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

As further discussed at Footnote 5(e) - Leases, the Company adopted Topic 842 on January 1, 2019 under the optional transition method and elected the short-term lease exception and available practical expedients. Under the transition method, the Company did not adjust its comparative period financial information or make the new required lease disclosures for periods before the effective date.

**NOTE 4 — STOCKHOLDERS' EQUITY:**

During the first six months of 2019 options to purchase 46,875 shares of the Company's common stock were exercised on a cashless basis into 24,075 shares of common stock. During the first six months of 2018, options to purchase 114,947 shares of the Company's common stock were exercised on a cashless basis into 71,650 shares of common stock.

On February 13, 2018, the Company closed on an underwritten registered public offering of 1,783,760 shares of its common stock at a public offering price of $6.75 per share for gross proceeds of approximately $12.0 million. The net proceeds, after underwriting discounts and commissions, were $10.9 million. The net proceeds were intended for business expansion and working capital, including product development; operational expansion or improvements, such as new automated equipment and a facilities update; clinical trials and other related activities; and, sales and marketing.

**NOTE 5 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:**

***a) Concentrations:***

The following table discloses product sales the Company had to each customer that purchased in excess of 10% of the Company's net product sales for the periods indicated:

| | For the three months ended | | | | For the six months ended | | | | Accounts Receivable as of | |
|---|---|---|---|---|---|---|---|---|---|---|
| | June 30, 2019 | | June 30, 2018 | | June 30, 2019 | | June 30, 2018 | | June 30, 2019 | Dec. 31, 2018 |
| | Sales | % of Sales | Sales | % of Sales | Sales | % of Sales | Sales | % of Sales | | |
| Customer 1 | $ 4,573,434 | 54% | $ 3,217,387 | 47% | $ 5,615,932 | 38% | $ 5,627,145 | 42% | $ 2,804,382 | $ 3,499,340 |
| Customer 2 | 1,627,075 | 19% | 1,460,630 | 21% | 3,460,666 | 23% | 1,460,630 | 11% | 1,746,939 | 1,033,824 |

Sales include product sales only, while accounts receivable reflects the total due from the customer, including freight.

The following table discloses purchases the Company made from each vendor that sold to the Company in excess of 10% of the Company's total purchases for the periods indicated:

| | For the three months ended | | | | For the six months ended | | | | Accounts Payable as of | |
|---|---|---|---|---|---|---|---|---|---|---|
| | June 30, 2019 | | June 30, 2018 | | June 30, 2019 | | June 30, 2018 | | June 30, 2019 | Dec. 31, 2018 |
| | Purchases | % of Purc. | Purchases | % of Purc. | Purchases | % of Purc. | Purchases | % of Purc. | | |
| Vendor 1 | $ * | *% | $ 548,605 | 18% | $ * | * | $ * | * | $ * | $ * |
| Vendor 2 | * | *% | 394,518 | 13% | * | *% | 863,875 | 14% | * | * |
| Vender 3 | * | *% | 326,282 | 11% | * | * | * | * | * | * |

In the table above, an asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated or that accounts payable by the vendor did not exceed 10% of total accounts payable at the date indicated.

The Company currently buys materials that are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms as the vendors shown in this table. A change in suppliers, however, could cause a delay in manufacturing, either from the logistics of changing suppliers or from product changes attributable to new components, which could result in a possible loss of sales, and which could adversely affect operating results.

***b) Governmental Regulation:***

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration, U.S. Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping, are subject to regulatory review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions, and criminal prosecution.

***c) Employment Contracts:***

The Company has multi-year contracts with two key employees that call for salaries presently aggregating $800,000 per year. The contracts expire in March 2020 and December 2021. The following table is a schedule of future minimum salary commitments as of June 30, 2019:

| | |
|---|---|
| 2019 | $ 400,000 |
| 2020 | 458,750 |
| 2021 | 345,000 |

***d) Pension Plan:***

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% of salary (or up to 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled approximately $49,000 and $46,000 for the six months ended June 30, 2019 and 2018, respectively.

***e) Leases:***

Chembio's leases have historically been limited to its facilities in New York, Germany, and Malaysia. As of June 30, 2019, the Company was a party to six leases. One of the leases is subject to a sublease for the remainder of its term, as further described below.

The Company's leases generally include optional renewal periods. Upon entering into a new lease, the Company evaluates the leasehold improvements and regulatory requirements related to its operations in that location. To the extent that the initial lease term of the related lease is less than the useful life of the leasehold improvements and potential regulatory costs associated with moving the facility, the Company concludes that it is reasonably certain that a renewal option will be exercised, and thus that renewal period is included in the lease term and the related payments are reflected in the right-of-use ("ROU") asset and lease liability.

The Company's leases generally include fixed rental payments with defined annual increases. While certain of the Company's leases are gross leases, the majority of the Company's leases are net leases in which the Company makes separate payments to the lessor based on the lessor's property and casualty insurance costs, the property taxes assessed on the property, and a portion of the common area maintenance where applicable. The Company has elected the practical expedient not to separate lease and nonlease components for all of the Company's facility leases. The Company has also elected the practical expedient for short-term lease exception for all of its facility leases.

During Q2 the Company adjusted the right-of-use asset to include deferred rent that was previously included in Prepaid and Other Current Assets on the consolidated Balance Sheet.

The components of lease expense for the three and six month periods ended June 30, 2019 were as follows:

| | Three Months Ended June 30, 2019 | Six Months Ended June 30,2019 |
|---|---|---|
| Operating lease cost | $ **400,658** | $ **682,261** |
| | | |
| Finance lease cost | | |
| Amortization of right-of-use assets | $ - | $ - |
| Interest on lease liabilities | - | - |
| Total finance lease cost | $ - | $ - |

Supplemental cash flow information related to leases was as follows.

| | Three Months Ended June 30, 2019 | Six Months Ended June 30,2019 |
|---|---|---|
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | $ **147,107** | $ **305,157** |
| Operating cash flows from finance leases | - | - |
| Financing cash flows from finance leases | - | - |
| Right-of-use assets obtained in exchange for lease obligations: | | |
| Operating leases | $ - | $ **6,949,611** |
| Finance leases | **233,722** | **233,722** |

Supplemental balance sheet information related to leases was as follows.

| | June 30, 2019 |
|---|---|
| **Operating Leases** | |
| Operating lease right-of-use assets | $ 6,949,611 |
| | |
| Current portion of operating lease liability | 389,051 |
| Operating lease liabilities | 6,582,446 |
| Total operating lease liabilities | $ 6,971,497 |
| | |
| **Finance Leases** | |
| Finance lease right of use asset | $ 233,722 |
| Accumulated depreciation | - |
| Finance lease right of use asset, net | $ 233,722 |
| Current portion of finance lease liability | 43,931 |
| Finance lease liability | 189,791 |
| Total finance lease liabilities | $ 233,722 |
| | |
| **Weighted Average Remaining Lease Term** | |
| Operating leases | 10 years |
| Finance leases | 5 years |
| | |
| **Weighted Average Discount Rate** | |
| Operating leases | 8.53% |
| Finance leases | 7.0% |

During the three months ended June 30, 2019, the Company executed an operating sublease related to its former Holbrook, NY facility. The sublease runs conterminously with the base lease in Holbrook, for which the Company remains primarily responsible. In addition, the Company has entered into a finance lease agreement relating to the office furniture in late June 2019. The Company has recognized the corresponding lease asset and liability effective June 30, 2019 and will commence to record related depreciation starting on July 1, 2019. Monthly payments towards this lease will also commence in July 2019.

The interest rates implicit in each of the leases are not readily determinable, and the Company does not have an established incremental borrowing rate as its only debt is a seller-financed note for manufacturing equipment. Therefore, the Company used an interest rate based on the marketplace for public debt.

Maturities of lease liabilities as of June 30, 2019 were as follows.

| | Operating Leases | Finance Leases |
|---|---|---|
| 2019 (excluding the six months ended June 30, 2019) | $ 316,100 | $ 27,768 |
| 2020 | 813,443 | 55,536 |
| 2021 | 998,071 | 55,536 |
| 2022 | 1,026,044 | 55,536 |
| 2023 | 1,011,085 | 55,535 |
| Thereafter | 6,792,767 | 27,768 |
| Total lease payments | $ 10,957,510 | $ 277,679 |
| Less imputed interest | (3,986,013) | (43,957) |
| Total | $ 6,971,497 | $ 233,722 |

As previously disclosed in the Company's 2018 Annual Report on Form 10-K, and under the previous lease accounting standard, future minimum lease payments for operating leases having initial or remaining non-cancellable lease terms in excess of one year would have been as follows for the years ending December 31:

| | |
|---|---|
| 2019 | $ 384,308 |
| 2020 | 88,576 |
| 2021 | - |
| | $ 472,884 |

***f) Litigation:***

From time to time, the Company is involved in certain legal actions arising in the ordinary course of business. The outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on the Company’s future financial position or results of operations.

**NOTE 6 — NOTE PAYABLE:**

In September 2017, the Company entered into an agreement with an equipment vendor to purchase automated assembly equipment for approximately $660,000. The terms call for payments of 30% down, 60% at time of factory acceptance testing and 10% after delivery. The vendor agreed to lend the Company 15%, 40%, and 10% of each originally scheduled payment, respectively. The Company paid interest at an annual rate of 12% until delivery. Beginning in September 2018, the Company began making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a twenty-four month period.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, or our Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report, particularly in the section titled "Item 1A. Risk Factors" in Part I of our Annual Report. The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date, and reported amounts of revenue and expenses during the reporting period.*

*Our management's discussion and analysis of financial condition and results of operations is intended to help you understand the business operations and financial condition of the Company as of June 30, 2019, and for the three and six months ended June 30, 2019. This discussion should be read in conjunction with Item 1. Financial Statements.*

The following discussion is presented in six sections:

- Executive Overview
- Consolidated Results of Operations
- Liquidity and Capital Resources
- Recent Developments
- Significant Accounting Policies and Critical Accounting Estimates
- Recently Issued Accounting Pronouncements

**Executive Overview**

***Our Business***

Through our wholly owned subsidiaries Chembio Diagnostic Systems Inc., Chembio Diagnostics Malaysia Sdn Bhd and Chembio Diagnostics GmbH, we develop, manufacture and commercialize point-of-care diagnostic tests that are used to detect or diagnose diseases. All products that are currently being developed are based on our patented DPP technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology.

***Business Strategy***

We are a leading provider of point-of-care diagnostic products for the detection and diagnosis of infectious diseases. We have been expanding our product portfolio based upon our proprietary DPP technology platform, which uses a small drop of blood from the fingertip to provide high-quality, cost-effective diagnostic results in approximately 15 minutes. We seek to build additional revenue streams by entering into strategic collaborations with leading global healthcare companies in order to leverage the DPP platform.

Compared with traditional lateral flow technology, the DPP technology platform provides enhanced sensitivity and specificity, advanced multiplexing capabilities, and, when used with the DPP Micro Reader, quantitative results. Our DPP HIV test provides sensitivity of 99.8% and specificity of 100%, and has been approved by the U.S. Food and Drug Administration, or FDA, and approved as a waived test under the Clinical Laboratory Improvement Amendments of 1988.

We are pursuing three corporate priorities:

- Expand our commercialization;
- Advance our research and development, or R&D pipeline; and,
- Prepare for additional growth.

Our accomplishments during the second quarter of 2019 included:

- Achieved total revenue of $9.6 million for the three months ended June 30, 2019, an increase of 10% over same period in the prior year;
- Entered collaboration with Takeda, a global pharmaceutical company, to develop a novel point-of-care test for an undisclosed biomarker;
- Received CE Mark for DPP Zika, Dengue, Chikungunya multiplex test; and
- Received ANVISA approval for DPP Dengue test.

Our product commercialization and product development efforts are focused in two areas: infectious disease, which includes both sexually transmitted and tropical & fever disease; and strategic collaborations with leading global healthcare companies, which leverage the DPP platform to provide us with additional revenue streams. In infectious disease, we are commercializing tests for HIV, Syphilis, Zika virus, dengue virus, chikungunya virus, , and ebola, and developing tests for hepatitis C, malaria, lassa, Marburg, leptospirosis, *Rickettsia typhi*, *Burkholderia pseudomallei*, and *Orientia tsutsugamushi*. Certain of these are also being developed as part of fever panel tests. Through strategic collaborations, we are developing tests for a specific form of cancer, concussions, bovine tuberculosis, and for eosinophilic respiratory disease, the latter in collaboration with global biopharmaceutical company AstraZeneca. As noted above, we are also developing a point-of-care test for an undisclosed biomarker for Takeda, also a global pharmaceutical company.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are indispensable for large-scale prevention and treatment programs. Our product development is focused on areas where the availability of rapid POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally, we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

Our products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers.

**Consolidated Results of Operations**

***Three Months Ended June 30, 2019 versus Three Months Ended June 30, 2018***

The results of operations for the three months ended June 30, 2019 and 2018 were as follows (dollars in thousands):

| | **June 30, 2019** | | June 30, 2018 | |
|---|---|---|---|---|
| TOTAL REVENUES | **$ 9,591** | **100%** | $ 8,720 | 100% |
| OPERATING COSTS AND EXPENSES: | | | | |
| Cost of product sales | **6,693** | **71%** | 5,935 | 68% |
| Research and development expenses | **2,101** | **22%** | 1,991 | 23% |
| Selling, general and administrative expenses | **4,097** | **43%** | 2,547 | 29% |
| | **12,891** | | 10,473 | |
| LOSS FROM OPERATIONS | **(3,300)** | | (1,753) | |
| OTHER INCOME | **6** | | 25 | |
| LOSS BEFORE INCOME TAXES | **(3,294)** | **(36)%** | (1,728) | (20)% |
| Income tax provision (benefit) | **(107)** | | - | |
| NET LOSS | **$ (3,187)** | | $ (1,728) | |

Percentages in the table reflect the percent of total revenues.

*Total Revenues*

Total revenues during the quarter ended June 30, 2019 were $9.6 million, an increase of $0.9 million, or 10%, compared to the quarter ended June 30, 2018. The increase in total net revenues was composed of the following:

- $1.6 million, or 23.8%, increase in product sales driven by gains in nearly every region, led by Latin America, Africa, and Europe. Latin America benefited from Dengue/Zika/Chikungunya multiplex and individual assay sales, together with supply chain-related catch-up HIV assay sales to Brazil. Africa continued its strength related to the Ethiopia program, and Europe reflects the contribution of our acquisition of opTricon GmbH (now Chembio Diagnostics GmbH) in November 2018.
- $0.8 million, or 41%, decrease in R&D and grant and license and royalty revenues, related to the timing and cadence of program performance obligations.

*Gross Product Margin*

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses.

Gross product margin is net product sales less cost of product sales, and gross product margin percentage is gross product margin as a percentage of net product sales. Gross product margin increased by $0.9 million, or 9.5% compared to 2018. The following schedule calculates gross product margin (dollars in thousands):

| | For the three months ended | | Favorable/(unfavorable) | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **$ Change** | **% Change** |
| Net product sales | $ 8,488 | $ 6,858 | $ 1,630 | 23.8% |
| Less: Cost of product sales | (6,693) | (5,935) | (758) | (12.8)% |
| Gross product margin | $ 1,795 | $ 922 | $ 873 | 9.5% |
| Gross product margin percentage | 21.1% | 13.5% | | |

The $0.9 million increase in gross product margin was composed of the following:

- $0.2 million favorable product sales volume as described above, and
- $0.7 million from 7.7% favorable product margins related to initial benefits from our first automated assembly line, reduced contract labor cost, and stable volume, offset in part by the impact of geographic mix on average selling prices.

As noted above, we have commenced automated manufacturing on our first line and have two other lines on order. We expect the automation to both reduce our reliance on manual labor and contribute to improving margins.

*Research and Development*

This category includes costs incurred for clinical & regulatory affairs and other research & development, as follows (dollars in thousands):

| | For the three months ended | | Favorable/(unfavorable) | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **$ Change** | **% Change** |
| Clinical & regulatory affairs | **$** 323 | $ 200 | $ (123) | $ 61.5% |
| Other research & development | 1,778 | 1,791 | 13 | -% |
| Total Research and Development | **$** 2,101 | $ 1,991 | $ (110) | 5.5% |

The increase in clinical & regulatory affairs costs for the three months ended June 30, 2019 compared to the three months ended June 30, 2018 was primarily associated with obtaining new regulatory approvals.

*Selling, General and Administrative Expense*

Selling, general and administrative expense, or SG&A, includes administrative expenses, sales and marketing costs (including commissions), and other corporate items.

The $1.6 million, or 59%, increase in SG&A for the three months ended June 30, 2019 compared to the three months ended June 30, 2018, was primarily associated with the inclusion of: costs from Chembio Diagnostics GmbH; legal, rent, and other costs related to the lease for our new Hauppauge, NY corporate headquarters, R&D labs, and manufacturing facility; and, higher non-cash equity compensation costs.

*Other Income*

Other income consists principally of interest income earned on our deposits, net of interest expense, which remained consistent in the second quarter of 2019 as compared to the second quarter of 2018.

*Income Tax Provision*

During the second quarter of 2019, we recognized a tax benefit of $0.1 million related to losses generated by our foreign subsidiaries. As of June 30, 2019 and 2018, our United States deferred tax assets included a full valuation allowance.

***Six Months Ended June 30, 2019 versus Six Months Ended June 30, 2018***

The results of operations for the six months ended June 30, 2019 and 2018 were as follows (dollars in thousands):

| | **June 30, 2019** | | June 30, 2018 | |
|---|---|---|---|---|
| TOTAL REVENUES | **$ 17,892** | **100%** | $ 16,437 | 100% |
| | | | | |
| OPERATING COSTS AND EXPENSES: | | | | |
| Cost of product sales | **11,464** | **65%** | 10,053 | 61% |
| Research and development expenses | **4,318** | **24%** | 3,838 | 23% |
| Selling, general and administrative expenses | **8,110** | **45%** | 4,954 | 30% |
| Acquisition Costs | **396** | **2%** | - | -% |
| | **24,288** | | 18,845 | |
| | | | | |
| LOSS FROM OPERATIONS | **(6,396)** | | (2,408) | |
| | | | | |
| OTHER INCOME | **13** | | 27 | |
| | | | | |
| LOSS BEFORE INCOME TAXES | **(6,383)** | **(36)%** | (2,381) | (14)% |
| | | | | |
| Income tax provision (benefit) | **(380)** | | - | |
| NET LOSS | **$ (6,003)** | | $ (2,381) | |

Percentages in the table reflect the percent of total revenues.

*Total Revenues*

Total revenues during the six months ended June 30, 2019 were $17.9 million, an increase of $1.5 million, or 9% compared to the six months ended June 30, 2018. The increase in total net revenues was composed of the following:

- $1.6 million, or 12%, increase in product sales, reflecting gains in Africa, the United States, and Europe, offset in part by lower sales in Asia and Latin America. Africa continued to benefit from our winning the single largest tender in our history for the supply of HIV tests to Ethiopia, together with meaningful commercial successes in that region. United States sales benefited from our winning back a large state program, and Europe reflects stable HIV self-testing and contribution from our acquisition of Chembio Diagnostics GmbH in November 2018. Asia and Latin America declines were affected by the timing of national tenders and demand scheduling differences, respectively.
- $0.1 million, or 5%, decrease in R&D and grant and license and royalty revenues, consistent with the discussion above related to the second quarter of 2019 compared to the second quarter of 2018.

*Gross Product Margin*

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses.

Gross product margin increased by $0.2 million, or 6%, compared to the first half of 2018. The following schedule calculates gross product margin (dollars in thousands):

| | **For the six months ended** | | **Favorable/(unfavorable)** | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **$ Change** | **% Change** |
| Net product sales | **$** 14,871 | $ 13,256 | $ 1,615 | 12.2% |
| Less: Cost of product sales | (11,464) | (10,053) | (1,411) | (14.0)% |
| Gross product margin | **$** 3,407 | $ 3,203 | $ 205 | 6.4% |
| Gross product margin percentage | 22.9**%** | 24.2% | | |

The $0.2 million increase in gross product margin was composed of the following:

- $0.4 million favorable product sales volume as described above, offset in part by
- $0.2 million from unfavorable product margins related to the impact of geographic mix on average selling price, partially offset by reduced contract labor to manually assemble our products and initial benefit from our first automated assembly line that started at the end of the first quarter of 2019.

The decreases in gross product margin and gross product margin percentage reflected increased labor (including contract labor) costs required to manually assemble our products and the impact of geographic mix on average selling prices. As noted above, we have commenced automated manufacturing on our first line and have two other lines on order. We expect the automation to both reduce our reliance on manual labor and contribute to improving gross product margin.

*Research and Development*

This category includes costs incurred for clinical & regulatory affairs and other research & development, as follows (dollars in thousands):

| | For the six months ended | | Favorable/(unfavorable) | |
|---|---|---|---|---|
| | **June 30, 2019** | June 30, 2018 | **$ Change** | **% Change** |
| Clinical & regulatory affairs | **$** 763 | $ 684 | $ (79) | 11.5% |
| Other research & development | 3,555 | 3,155 | (400) | 12.7% |
| Total Research and Development | **$** 4,318 | $ 3,839 | $ (479) | 11.1% |

The increase in clinical & regulatory affairs costs for the six months ended June 30, 2019 compared to the six months ended June 30, 2018 was primarily associated with obtaining new regulatory approvals. The increase in other R&D costs related to customer programs.

*Selling, General and Administrative Expense*

The $3.1 million, or 63.3%, increase in SG&A for the six months ended June 30, 2019 compared to the six months ended June 30, 2018, was primarily associated with the inclusion of: costs from Chembio Diagnostics GmbH; legal, rent, and other costs related to the lease for our new Hauppauge, NY corporate headquarters, R&D labs, and manufacturing facility; and, higher non-cash equity compensation costs.

*Acquisition Costs*

Acquisition costs for the six months ended June 30, 2019 included legal, due diligence, audit, and related costs associated with acquisitions. The $0.4 million increase in acquisition costs for the six months ended June 30, 2019 as compared to 2018 is associated with the acquisition of Chembio Diagnostics GmbH in November 2018.

*Other Income*

Other income consists principally of interest income earned on our deposits, net of interest expense, which remained consistent in the first half of 2019 as compared to the first half of 2018.

*Income Tax Provision*

During the first half of 2019, we recognized a tax benefit of $0.4 million related to losses generated by our foreign subsidiaries. As of June 30, 2019 and 2018, our United States deferred tax assets included a full valuation allowance.

**Liquidity and Capital Resources**

During the six months ended June 30, 2019, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used cash flow of $7.2 million. As of June 30, 2019, we had no outstanding debt (excluding leases) other than a $0.3 million seller-financed note payable incurred in connection with our purchase of automated manufacturing equipment.

We continually evaluate our liquidity requirements, capital needs and availability of capital resources based on our operating needs and our planned growth initiatives. We believe our existing cash and cash equivalents and our cash flow from operating activities will be sufficient to meet our anticipated cash needs for at least the next twelve months. We are, as part of our efforts to accelerate growth of our business consistent with our long-term operating plan, currently evaluating the desirability of credit facility or other debt financing alternatives that would leverage our existing capital structure. We have not secured any commitment for a debt financing at this time, nor can we provide any assurance that any debt financing would be available on commercially acceptable terms or at all.

Our future working capital needs will depend on many factors, including the rate of our business and revenue growth, the timing of our continuing automation of U.S. manufacturing, and the timing of investment in our research and development as well as sales and marketing. If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, or if we choose not to, or are unable to, complete a debt financing, we may not be able to generate the cash flow needed to fund our automation of U.S. manufacturing and our investment in research and development and sales and marketing at the time contemplated by our operating plan. In such an event, we may elect to reduce the level, or otherwise delay the timing, of such funding and/or such investments, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow.

If we do not elect to reduce or delay such funding or investments, or if we determine to effect one or more acquisitions of businesses, technologies or products, we may be required to seek to raise additional funds through public or private financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we were to raise additional funds through the issuance of equity or convertible securities, the issuance could result in substantial dilution to existing stockholders, and the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of common stock.

*Sources of Funds*

**Research and Development Awards.** We frequently seek research and development programs that may be awarded by government, non-governmental organizations, and non-profit entities, including private foundations. During the six months ended June 30, 2019, we recognized grant revenue totaling $1.2 million from government, non-governmental organizations, and non-profit entities.

**Working Capital**. The following table sets forth selected working capital information:

| | June 30, 2019 |
|---|---|
| | *(in thousands)* |
| Cash and cash equivalents | $ 4,504 |
| Accounts receivable, net of allowance for doubtful amounts | 7,734 |
| Inventories, net | 9,071 |
| Prepaid expenses and other current assets | 570 |
| Total current assets | 21,879 |
| Less: Total current liabilities | (6,477) |
| Working capital | $ 15,402 |

Current liabilities include $0.4 million current portion of operating and finance lease liabilities in accordance with Accounting Standards Codification Topic 842, *Leases,* which was adopted effective January 1, 2019.

Our cash and cash equivalents at June 30, 2019 were unrestricted and held for working capital purposes. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable balance fluctuates from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, client mix, and the timing of shipment of our products and the invoicing of our research and development activities.

*Uses of Funds*

**Cash Flow Used in Operating Activities**. Our operations used $7.2 million of cash during the six months ended June 30, 2019, due to the net loss adjusted for non-cash items for the six months of $4.9 million, a $0.3 million increase in accounts receivable related to an 8.8% increase in total revenue, a $1.2 million increase in inventory also associated with the increase in total revenue, $0.1 million increase in prepaid expenses, other current assets and deposits related to prepaid rent and security deposits for our new Hauppauge corporate headquarters facility, and a $0.6 million decrease in accounts payable and accrued liabilities.

**Capital Expenditures**. During the six months June 30, 2019, we continued to invest in manufacturing equipment and other fixed assets. Our capital expenditures totaled $1.1 million in the six months ended June 30, 2019.

**Effects of Inflation**

Inflation and changing prices have not had a material effect on our business, and we do not expect that they will materially affect our business in the foreseeable future. Any impact of inflation on cost of revenue and operating expenses, especially employee compensation costs, may not be readily recoverable in the price of our product offerings.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934.

**Critical Accounting Estimates**

There were no significant changes in our critical accounting estimates during the three months ended June 30, 2019 to augment the critical accounting estimates disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, other than those described in the Notes to the condensed consolidated financial statements included in this report.

**Recently Issued Accounting Pronouncements**

A discussion of recent accounting pronouncements is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and is updated in the Notes to the condensed consolidated financial statements included in this report.

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.**

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, have no material derivative risk to report under this Item. As of June 30, 2019, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows.

We are exposed to market risks from changes in currency exchange rates and certain commodity prices. All sales from our U.S. subsidiary, regardless of the customer location, are denominated in U.S. dollars. Sales denominated in foreign currencies are associated with the sales from our subsidiaries, Chembio Diagnostics Malaysia Sdn Bhd and Chembio Diagnostics GmbH, and composed approximately 7% of our total revenues for the six months ended June 30, 2019.

**ITEM 4. CONTROLS AND PROCEDURES**

**(a) Disclosure Controls and Procedures**. Under the supervision and with the participation of our senior management, consisting of our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of June 30, 2019 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**(b) Changes in Internal Control over Financial Reporting**. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the three months ended June 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We know of no material, existing or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest that is adverse to our interest.

**ITEM 1A. RISK FACTORS**

There have been no material changes to the risk factors discussed in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2018. In addition to the other information set forth in this report, you should carefully consider those risk factors, which could materially affect our business, financial condition and future operating results. Those risk factors are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may have a material adverse effect on our business, financial condition and operating results.

**ITEM 6. EXHIBITS**

| Number | Description |
|---|---|
| 31.1 | Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Presentation Linkbase Document |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Chembio Diagnostics, Inc.

Date: August 6, 2019

By:/s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President

Date: August 6, 2019

By: /s / Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and
Executive Vice President

**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John J. Sperzel, certify that:

1. I have reviewed this quarterly report Form 10-Q of Chembio Diagnostics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(e) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

Date: August 6, 2019

/s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President
*(Principal Executive Officer)*

**Exhibit 31.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Neil A. Goldman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Chembio Diagnostics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

Date: August 6, 2019

/s/ Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and Executive Vice President
*(Principal Financial Officer)*

**Exhibit 32**

**CERTIFICATION PURSUANT TO 18 U.S.C. 1350,**
**AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Chembio Diagnostics, Inc. for the quarterly period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge on the date hereof:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the period presented therein.

Date: August 6, 2019

/s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President
*(Principal Executive Officer)*

Date: August 6, 2019

/s/ Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and Executive Vice President
*(Principal Financial Officer)*

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Sec. 1350 and is not being filed as part of the Report or as a separate disclosure document.